UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLSETON DIVISION

LAURA COX and JEFFERY DEAN COX, *Plaintiffs,* v. JOHNSON & JOHNSON, INC. and ETHICON, INC., *Defendants.*	)	MDL: 2327 Case No.: 2:12-cv-03808

COMPLAINT

COME NOW Plaintiffs herein and hereby files this Complaint, showing the Court as follows:

I.

PARTIES

1. Plaintiff Laura Cox (hereinafter referred to as "Plaintiff") and Plaintiff Jeffery Dean Cox are residents of the State of Tennessee.

2. Defendant Johnson & Johnson, Inc. is a corporation existing under the laws of the State of New Jersey, with its principal place of business at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey.

3. Defendant Ethicon, Inc., a subsidiary of Defendant Johnson & Johnson, Inc., is a corporation existing under the laws of New Jersey, with its principal place of business at Route 22 West, Somerville, New Jersey.

4. Defendants Johnson & Johnson, Inc. and Ethicon, Inc. will collectively be referred to as "Defendants".

II.

JURISDICTION AND VENUE

5. This is a lawsuit for personal injury damages in excess of $75,000.00. The parties are citizens of different states.

6. At all times material hereto, Defendants did business in the State of Tennessee. Additionally, Defendants had contacts and did business in West Virginia. Accordingly, this Court has diversity jurisdiction pursuant to 28 U.S.C § 1332.

7. Venue is proper pursuant to the Order on the Judicial Panel on Multidistrict Litigation and Pretrial Order #1, paragraph 2, dated February 29, 2012, entered by Honorable Judge Joseph R. Goodwin.

8. All conditions precedent to the maintenance of this action have occurred, have been performed, or have been waived.

III.

FACTUAL BACKGROUND

9. At all relevant times, Defendants were in the business of and did create, design, manufacture, test, formulate, advertise, market, promote, sell and/or distribute the Gynecare TVT (hereinafter referred to as "Product"), designed to treat stress urinary incontinence.

10. Defendants' Product has been and continues to be marketed to the medical community and to patients as safe, effective, reliable, medical devices; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, and safer and more effective as compared to the traditional products and procedures for treatment.

11. Defendants knew or should have known that the Product was insufficiently tested; that it was defectively created, designed, manufactured, tested, and formulated; lacked adequate warnings; and was negligently and recklessly advertised, marketed, promoted and sold.

12. Defendants' Product has high failure, injury, and complication rates, failed to perform as intended, require frequent and often debilitating re-operations, and has caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff.

13. On October 20, 2008 the FDA issued a public health notification alerting the medical community that transvaginal placement of mesh device systems, including the Product, could lead to potentially serious complications including erosion of the material, infection, pain, urinary complications, and recurrence of prolapse or incontinence.

14. Upon information and belief, Defendants misrepresented the risks inherent in the use of the Product in its applications for approval to the FDA and to other governmental persons and/or agencies.

15. Defendants have consistently underreported and withheld information about the propensity of Defendants' Product to fail and cause injury and complications, and have misrepresented the efficacy and safety of the Product, through various means and media, actively and intentionally misleading the FDA, the medical community, patients and the public at large.

16. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Defendants' Product.

17. Defendants failed to design and establish a safe, effective procedure for removal of the Defendants' Product; therefore, in the event of a failure, injury or complaint it is impossible to easily and safely remove Defendants' Product.

18. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for implantation and treatment of female urinary incontinence and similar conditions have existed at all times relevant.

19. Defendants' Product was at all times utilized and implanted in a manner foreseeable to the Defendants.

20. Defendants have at all times provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Defendants' Product, and thus increase the sales of the Product.

21. The injuries, conditions and complications suffered due to Defendants' Product includes but is not limited to mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia, blood loss, neuropathic and other acute and chronic nerve damage, pelvic floor damage, pelvic pain, urinary and fecal incontinence, prolapse of organs, and often additional intensive medical treatment, including but not limited to operations to locate and remove mesh, attempts to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications.

22. Despite Defendants' knowledge of these injuries, conditions, and complications caused by their Product, the Defendants have, and continue to manufacture, market, and sell the Product, while continuing to fail to adequately warn, label, instruct and disseminate information with regard to the Defendants' Product, both prior to and after the marketing and sale of the Product.

23. On or about February 3, 2005, Plaintiff was implanted with Defendants' Product at Maury Regional Hospital located in the State of Tennessee.

24. The Product was implanted in Plaintiff to treat her stress urinary incontinence, the use for which the Product was designed, marketed and sold.

25. As a result of having the Product implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has suffered financial or economic loss, including, but not limited to, and obligations for medical services and has endured impaired physical relations with her husband, Plaintiff Jeffery Dean Cox.

IV.

DISCOVERY RULE, TOLLING AND FRAUDULENT CONCEALMENT

26. Plaintiffs incorporate by reference all of the above paragraphs as if set forth in full herein.

27. Plaintiffs assert all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

28. Plaintiffs plead that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiffs had been injured, the cause of the injury, and the tortuous nature of the wrongdoing that caused the injury.

29. Despite diligent investigation by Plaintiffs into the cause of their injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiffs' injuries and damages, and their relationship to the Product was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiffs' claims. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable statutory limitations period.

30. The running of the statute of limitations in this cause is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiffs and Plaintiff's physicians of the true risks associated with the Product. As a result of Defendants' fraudulent concealment, Plaintiffs and Plaintiff's prescribing physicians were unaware, and could not have known or have learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendants.

31. The running of the statute of limitations in this cause may be tolled due to the pendency of a class action proceeding against one or more of the Defendants herein. Class Action tolling is proper where Plaintiffs are members of an asserted class and the claims asserted in the class action proceeding are the same as the claims asserted in this action.

32. Defendants are estopped from asserting a statute of limitations defense because Defendants fraudulently concealed from Plaintiffs the nature of Plaintiffs' injuries and the connection between the injuries and Defendants' tortious conduct.

V.

CAUSES OF ACTION

COUNT I: NEGLIGENCE

33. Plaintiffs incorporate by reference paragraphs 1–32 of this Complaint as if fully set forth herein.

34. The negligence and carelessness of the Defendants, jointly, severally, acting in concert and via their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

a. Designing, manufacturing, supplying, and distributing the Product in a defective condition when they knew or should have known of said defects;

b. Failing to act reasonably to identify, eliminate, or reduce the risks of hazards associated with the intended and foreseeable uses of the Product;

c. Failing to utilize existing technology or to apply established engineering, scientific and medical principles to eliminate or reduce the risks and hazards associated with the intended and foreseeable uses of the Product;

d. Designing, manufacturing, supplying, and distributing the Product, which was unreasonably dangerous, unsafe, and defective with regard to all of its intended and foreseeable purposes and uses;

e. Designing, manufacturing, supplying and distributing the Product without proper safeguards, safety devices, safety appliances, and safety equipment;

f. Designing, manufacturing, supplying, and distributing the Product, which was improper for the purpose(s) for which Defendants knew it would be used;

g. Designing, manufacturing, supplying and distributing the Product without adequate warnings;

h. Negligently designing, manufacturing, supplying and distributing the Product;

i. Failing to advise Plaintiff's physician of the dangers associated with the use of the Product;

j. Failing to advise Plaintiff of the dangers associated with the use of the Product, which deprived her of an opportunity to make an informed choice with regard to the surgery;

k. Failing to comply with standards, specifications and regulations in the industry;

l. Failing to comply with federal and state statutes and regulations;

m. Failing to adequately test the Product; and

n. Failing to conduct adequate post-marketing surveillance of the Product.

35. As a direct and proximate result of the negligence and carelessness of the Defendants, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses.

COUNT II: STRICY LIABILITY – DEFECTIVE DESIGN

36. Plaintiffs incorporate by reference paragraphs 1–35 of this Complaint as if fully set forth herein.

37. At all times relevant herein, Defendants were responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling the Product.

38. The Product is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design.

39. At all times relevant herein, the Product was expected to reach, and in fact did reach, consumers in the State of Tennessee and throughout the United States without substantial change in the condition in which it was sold.

40. At all times relevant herein, Defendants intended for their Product to be surgically implanted into members of the general public, including Plaintiff, and knew or should have known that the Product would be surgically implanted into members of the general public, including Plaintiff.

41. The implantation of the Product into Plaintiff was reasonably foreseeable and it was used in the manner for which it was intended by the Defendants.

42. At all times relevant herein, the Product was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following:

a. When placed in the stream of commerce, the Product contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting individuals, including Plaintiff to risks that exceeded the benefits of the Product, including but not limited to the risks of developing serious and dangerous side effects, serious infection, the need for additional procedures to remove and replace the Product, and/or the need for additional surgery as well as other severe and permanent health consequences;

b. When placed in the stream of commerce, the Product was defective in design, making the use of the Product more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with alternatives;

c. The Product's defects existed before it left the control of Defendants;

d. The Product was insufficiently tested;

e. The Product caused harmful side effects that outweighed any potential utility; and

f. The Product was not accompanied by adequate instruction and/or warnings to fully apprise consumers, including Plaintiffs herein, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiffs.

43. In addition, at the time the Product left the control of the Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the Product. These safer alternative designs were economically and technologically feasible, and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the Product's utility.

44. As a direct and proximate result of the negligence and carelessness of the Defendants, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses.

COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT

45. Plaintiffs incorporate by reference paragraphs 1–44 of this Complaint as if fully set forth herein.

46. At all times relevant herein, the Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling the Product.

47. At all times relevant herein, the Product was expected to reach, and did reach, consumers in the State of Tennessee and throughout the United States without substantial change in the condition in which it was sold.

48. The implantation of the Product into Plaintiff was reasonably foreseeable and it was used in the manner for which it was intended by the Defendants.

49. At all times relevant herein, the Product was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in

defective and unreasonably dangerous conditions at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following:

a. When placed in the stream of commerce, the Product contained manufacturing defects which rendered the Product unreasonably dangerous and subjected Plaintiff to risks that exceeded the benefits of the Product, including but not limited to the risks of developing serious and dangerous side effects, serious infection, the need for additional procedures to remove and replace the Product, and/or the need for additional surgery as well as other severe and permanent health consequences;

b. The Product's manufacturing defects occurred while the Product was in the possession and control of the Defendants;

c. The Product was not made in accordance with Defendants' specifications or performance standards; and

d. The Product's manufacturing defects existed before it left the control of Defendants.

50. As a direct and proximate result of the negligence and carelessness of the Defendants, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses.

COUNT IV: STRICY LIABILITY – FAILURE TO WARN

51. Plaintiffs incorporate by reference paragraphs 1–50 of this Complaint as if fully set forth herein.

52. The Product was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert consumers, including Plaintiffs herein, of the dangerous risks and reactions associated with the Product including but not limited to its propensity to cause injury, subjecting Plaintiff to risks that exceed the benefits of the Product, including but not limited to the risks of developing serious and dangerous side effects, serious infection, the need for additional procedures to remove and replace the Product and/or the need for additional surgery as well as other severe and permanent health consequences, notwithstanding Defendants' knowledge of an increased risk of these injuries and side effects over other forms of treatment for female urinary incontinence.

53. At all times relevant herein, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling the Product.

54. At all times relevant herein, Defendants intended for the Product to be surgically implanted into members of the general public, including Plaintiff, and knew or should have known that the Product would be surgically implanted into members of the general public, including Plaintiff.

55. Placement of the Product into Plaintiff was reasonably foreseeable and it was used in the manner for which it was intended by Defendants.

56. Plaintiffs could not, by the exercise of reasonable care, have discovered the defects herein mentioned and perceived their danger.

57. Defendants, as manufacturer, designer, distributor, and/or seller of the Product, are held to the level of knowledge of experts in the field.

58. Plaintiff, individually and through her physicians, reasonably relied upon the skill, superior knowledge and judgment of Defendants.

59. The warnings that were given by Defendants were not accurate, clear and/or were ambiguous.

60. The warnings that were given by Defendants failed to properly warn physicians of the increased risks associated with the Product, subjecting Plaintiff to risks that exceeded the benefits of the Product, including but not limited to the risks of developing serious and dangerous side effects, serious infection, the need for additional procedures to remove and replace the Product and/or the need for additional surgery as well as other severe and permanent health consequences.

61. Defendants had a duty to warn Plaintiffs of the dangers associated with the Product.

62. Had Plaintiff received adequate warnings regarding the risks of the Product, she would not have used it.

63. As a direct and proximate result of the negligence and carelessness of the Defendants, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses.

COUNT V – BREACH OF IMPLIED WARRANTY

64. Plaintiffs incorporate by reference paragraphs 1–63 of this Complaint as if fully set forth herein.

65. In manufacturing, marketing, distributing and selling the Product, Defendants owed a duty to users, including Plaintiff, to provide products which were fit for the ordinary

purpose for which they were used, and to ensure that the products conformed to the promises and affirmations made to the ultimate consumer, in this case Plaintiff.

66. Defendants knew or should have known that the general public and Plaintiff in particular relied on them to provide products which were fit for their ordinary or intended use and which would conform to the promises and affirmations concerning them.

67. Defendants, as more specifically set forth above, breached their duties and implied warranty of merchantability.

68. As a direct and proximate result of Defendants' breaches of their duties and implied warranties of merchantability, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses.

COUNT VI – BREACH OF EXPRESS WARRANTY

69. Plaintiffs incorporate by reference paragraphs 1–68 of this Complaint as if fully set forth herein.

70. Defendants expressly warranted that the Product was safe and suitable for use as reinforcement for human tissue in certain types of surgery associated with stress urinary incontinence.

71. The Product failed to conform to the express warranties of the Defendants.

72. As a direct and proximate result of Defendants' breaches of their duties and implied warranties of merchantability, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses.

COUNT VII – FRAUDULENT MISREPRESENTATION

73. Plaintiffs incorporate by reference paragraphs 1-72 of this Complaint as if fully set forth herein.

74. At all relevant times, Defendants jointly, severally, acting in concert, with or through others, their agents, servants, and/or employees made false and fraudulent representations to the medical community and eventual recipients of the Product, including but not limited to representations that the Product and its components had been tested and found to be safe and effective products for surgery.

75. Defendants knew or should have known these misrepresentations to be false. Nevertheless, Defendants willfully, wantonly, and recklessly disregarded the falsity of their statements; made representations fraudulently and deceitfully with the intent to induce women to seek surgical treatment involving the Product, and did in fact induce them; and induced the medical community to recommend, dispense, purchase, and provide surgical treatment to these women. All of Defendants' above acts and/or omissions evince a callous, reckless, willful, and depraved indifference to the life, health, safety and welfare of the system's intended recipients, including the Plaintiff herein.

76. At the time Defendants made their misrepresentations, recipients of the Product, including Plaintiff, could not by the exercise of their own reasonable care discover the falsity of Defendants' misrepresentations and, instead, reasonably believed them to be true.

77. The Defendants sought and in fact did obtain FDA approval of the Product in its defective form, based on Defendants' fraudulent misrepresentations, and Defendants inserted the system into the stream of commerce, causing harmful effects to recipients thereof. Defendants knew or should have known that the Product had been insufficiently tested, lacked adequate

warnings, and would lead to serious injury amongst its recipients. Defendants thereby breached their duty to Plaintiff, other recipients of the system and the medical community.

78. As a direct and proximate result of Defendants' fraudulent conduct and misrepresentations, made jointly, severally, acting in concert, with or through others, their agents, servants and/or employees, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses.

COUNT VIII – LOSS OF CONSORTIUM

79. Plaintiffs incorporate by reference paragraphs 1-78 of this Complaint as if fully set forth herein.

80. Plaintiff Jeffery Dean Cox is the spouse of Plaintiff, and as a direct and proximate result of Defendants' conduct as described in this Complaint, Plaintiff Jeffery Dean Cox has necessarily paid and has become liable to pay for medical aid, treatment, attendance and medications, and will necessarily incur further expenses of a similar nature in the future.

81. As a direct and proximate result of Defendants' conduct as described in this Complaint, Plaintiff Jeffery Dean Cox suffered and will suffer the loss of his wife's affection, companionship, services, society and other damages.

82. As a direct and proximate result of Defendants' conduct as described in this Complaint, Plaintiff Jeffery Dean Cox is entitled to and hereby seeks all such compensatory damages, punitive damages, attorney fees, reimbursement for all past, present and future health and medical costs related to the Product, and any and all damages allowed by law, in an amount to be determined at trial.

CONCLUSION AND PRAYER

WHEREFORE, Plaintiffs request a trial by jury and that the Court grants them the following relief against the Defendants, on all counts of this Complaint, including:

(A) Money Damages representing fair, just, and reasonable compensation for her respective common law and statutory claims in excess of $75,000;

(B) Lost Wages;

(C) Punitive and/or Treble Damages pursuant to state law;

(D) Attorneys' fees pursuant to state law;

(E) Pre-judgment and post-judgment interests as authorized by law on the judgments which enter on Plaintiffs' behalf;

(F) Costs of suit and expenses;

(G) Delay Damages; and

(H) Such other relief as is deemed just and appropriate.

PLAINTIFFS DEMAND A TRIAL BY JURY

Date: July 30, 2012

Respectfully submitted,

/s/ Clayton A. Clark, Esq.

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